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| APPLICATION NO.       | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|-------------|----------------------|---------------------|------------------|
| 10/593,426            | 06/13/2007  | Fabio Papes          | 059994-0155         | 7377             |
| 22428                 | 7590        | 10/14/2009           | EXAMINER            |                  |
| FOLEY AND LARDNER LLP |             |                      | ZHENG, LI           |                  |
| SUITE 500             |             |                      |                     |                  |
| 3000 K STREET NW      |             |                      | ART UNIT            | PAPER NUMBER     |
| WASHINGTON, DC 20007  |             |                      | 1638                |                  |
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|                       |             |                      | 10/14/2009          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/593,426             | PAPES ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | LI ZHENG               | 1638                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 15 June 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-28 is/are pending in the application.  
 4a) Of the above claim(s) 8-17, 28 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-7 and 18-27 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 19 September 2006 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/20/2009</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____ .                        |

**DETAILED ACTION**

1. Claims 1-28 are pending.

***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-7 and 18-27, and SEQ ID NO: 2 in the reply filed on 6/15/2009 is acknowledged.

The traverse is on the ground(s) that the technical feature is more than just a plant promoter given that all the promoters confer cambium/xylem-preferred expression (response, page 2, 3<sup>rd</sup> paragraph).

The Office contends that the claims do not recite the limitation that the promoters confer cambium/xylem-preferred expression.

Further, Applicants request withdrawal of the restriction to one of the groups of related sequences as identified as SEQ ID NO: 1-12, given that they are isolated from *Populus* and confer cambium/xylem-preferred expression (response, page 3, 3<sup>rd</sup> paragraph).

Applicants are reminded that different nucleotide sequences and amino acid sequences are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute different inventive concepts.

The requirement is still deemed proper and is therefore made FINAL.

***Specification***

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The hyperlink shown on Specification page 14.

***Claim Objections***

4. Claim 1 is objected to because it contains non-elected sequences.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2-3, 5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2: the recitation, "does not normally regulate", renders the claim indefinite. It is unclear what the recitation encompasses and what can be considered as "normally regulate. The metes and bounds are not clear. It is suggested that the recitation be replaced by – is heterologous to --

Claim 5 recites the limitation "the expression vector" in line 2. There is insufficient antecedent basis for this limitation in the claim.

#### ***Written Description***

6. Claims 1-7 and 18-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A review of the full content of the specification indicates that use of promoter sequences of SEQ ID NO: 2 is essential for practice the invention.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." (See *University of*

*California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997)). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” Id.

A review of the language of claims indicates that the claims are broadly drawn to a genus of sequences that hybridize under stringent condition to “a nucleotide sequence set forth in SEQ ID NO: 2” (emphasis added), a genus of sequences that is a fragment of at least 20 consecutive bases of SEQ ID NO: 2 that is capable of initiating transcription of a gene in a plant cell, as well as a genus of sequences that are at least 65% identical to SEQ ID NO: 2.

Given that “a nucleotide sequence set forth in SEQ ID NO: 2” encompasses any dinucleotide sequence in SEQ ID NO: 2 and that without a defined stringent condition, any sequence can hybridize to another sequence, the claims read on any sequence with plant promoter activity.

The specification teach identification of 12 putative cambium/xylem preferred promoters through bioinformatic analysis of EST clusters (Example 1). The specification further teach that those 12 promoters were isolated by PCR amplification (paragraphs[0051]-[0052]). The specification further teach GUS expression assay of those promoters in *Arabidopsis* plants (Example 4).

However, the specification does not describe the structure of any other species in the claimed genus except for SEQ ID NO:2, itself. Neither the specification nor the prior art teaches the conserved structures that are essential for the promoter activity. The only structures correlated with the promoter activity are the sequence of SEQ ID NO: 2. Not a single specie differing in sequence from SEQ ID NO: 2 and having their promoter activity is described in the specification. Therefore, given the breadth of the claim and the lack of further guidance, a person skilled in the art would conclude that applicants are not in possession of the claimed genera of promoters.

#### ***Scope of enablement***

7. Claim 1-7 and 18-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 2 and a fragment thereof having cambium/xylem preferred promoter in plant and the plants and bacteria as the transgenic host comprising the promoter, does not reasonably provide enablement for any other variants of SEQ ID NO: 2 having cambium/xylem promoter activity or transgenic host cell other than plants and bacteria . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the

invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.\

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The claims are broadly drawn to a genus of sequences that hybridize under stringent condition to “a nucleotide sequence set forth in SEQ ID NO: 2” (emphasis added), a genus of sequences that is a fragment of at least 20 consecutive bases of SEQ ID NO: 2 that is capable of initiating transcription of a gene in a plant cell, as well as a genus of sequences that are at least 65% identical to SEQ ID NO: 2.

Given that “a nucleotide sequence set forth in SEQ ID NO: 2” encompasses any dinucleotide sequence in SEQ ID NO: 2 and that without a defined stringent condition, any sequence can hybridize to another sequence, the claims read on any sequence with plant promoter activity.

Further, without defining hybridization condition, functional equivalent and substantial similarity, the claims reads on any constitutive promoter. The specification clearly does not teach all constitutive promoters. Undue experimentation would be required to determine all the constitutive promoters in all plant.

Furthermore, even the hybridization condition were defined to be a stringent one, it would still not be enabled. The state-of-the-art teaches isolating DNA fragments using stringent hybridization conditions, does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe.

Fourgoux-Nicol et al. (1999, *Plant Molecular Biology* 40 :857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65°C (page 859, left column, 2<sup>nd</sup> paragraph). Fourgoux-Nicol et al also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotides mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2). In the present example, the isolated fragment of Fourgoux-Nicol et al exhibits less than 50% sequence identity with the probe to which the fragment hybridized. It is well known in the art that the promoter element essential for its function could be very small (Kim et al. 1994, *Plant Molecular Biology* 24: 105-117, abstract). For example, the DNA that has at least 50% sequence identity to the nucleotide sequence of SEQ ID NO: 2 could have more than 1255 unmatched bases that are scattered along said nucleotide sequence. Since neither the specification nor the prior art teaches all the motifs required for promoter activity, it is not known which bases are indispensable for such promoter activity along the promoter region and which

bases are not. Therefore, in the absence of further guidance, undue experimentation would be required by one skilled in the art to make and use the claimed invention with DNA that has at least 50% sequence identity to the nucleotide sequence of SEQ ID NO: 2.

Further, the specification did not indicate that reverse complement DNA strands of SEQ ID No. 2 also have promoter activity, so nucleotide sequences hybridizable to SEQ ID No. 2 are expected to be reverse complement to those sequences and therefore is unlikely to have promoter activity. Undue experimentation would be required to use nucleotide sequences hybridizable to SEQ ID No. 2 to produce constitutive expression cassettes.

Further, the claimed expression cassette is for regulating cambium/xylem preferred expression in plants, however, instant claims read on any transgenic host cell. The transgenic non-plant cell such as mammals, nematodes and fungal cells are not enabled since a plant promoter is not expected to function similarly in other host cells including unicellular organisms which do not form tissues.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-7 and 18-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Xue et al (2002, US Patent Number 6,420,629).

Xue et al. teach that 4CL promoter that is highly specific for xylem expression in tobacco (column 8, lines 62-64). Xue et al. also teach expression vector using 4CL promoter and transgenic spruce expressing the vector (column 12, lines 33-58). Given that “a nucleotide sequence set forth in SEQ ID NO: 2” encompasses any dinucleotide sequence in SEQ ID NO: 2 and that without a defined stringent condition, any sequence can hybridize to another sequence, the claims read on any sequence with plant promoter activity. The reference thus meet all the limitations set forth by instant claims.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Li Zheng/

Examiner, Art Unit 1638